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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Spear et al.		Confirmation No.:	3399
Serial No.:	09/924,231	Art Unit:	1648
Filed:	August 8, 2001	Examiner:	Wortman, D.
For:	Pharmaceutical Compositions Comprising Herpes Virus Entry Receptor Protein	Attorney Docket No.:	7853-239

REPLY TO OFFICE ACTION UNDER 37 C.F.R. §1.116

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In response to the Office Action mailed on October 18, 2002 in connection with the above-identified application, please consider the remarks below. Applicants submit herewith (1) a Petition for Extension of Time for three months from January 18, 2003, up to and including April 18, 2003; and (2) a Notice of Appeal.

REMARKS

Claims 1-5 are pending in this application.

THE REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH SHOULD BE WITHDRAWN

Claims 1-5 are directed to pharmaceutical compositions comprising a recombinant soluble human HVEM polypeptide. While acknowledging that the specification teaches how to make the claimed pharmaceutical compositions, the Examiner contends that the specification fails to provide guidance that would enable the skilled artisan on how to use the compositions, because the the specification does not "teach a how to use a pharmaceutical composition comprising HVEM to achieve a beneficial result." The Examiner states that the cell culture assays disclosed in the specification do not provide a reasonable expectation of success in achieving a beneficial result in treating human viral infections. Further, the

Examiner states that "neither Applicant's arguments, a Declaration, nor supporting documents can be relied upon to supply what the specification does not teach."

The Examiner Has Not Established A *Prima Facie* Case of Non-Enablement

The Examiner states in the outstanding Office Action that Applicants' argument in the August 5, 2002 reply that MPEP 2164.01(c) precludes a rejection for nonenablement based on how to use when any enabled use is presented that would reasonably correlate with the entire scope of that claim is inapposite because the claims are drawn to a pharmaceutical composition comprising HVEM protein rather than the HVEM protein itself.

By emphasizing the distinction between *in vitro* and *in vivo* uses of the claimed pharmaceutical compositions, the Examiner predicates her position on the existence of a heightened how-to-use standard for pharmaceutical compositions. The case law does not support the Examiner's position. Nor has the Examiner provided any support for this contention.

The case law clearly distinguishes between claims drawn to a compound and claims drawn to the therapeutic use of the compound, the latter requiring a greater burden. *See, e.g.*, In re Bundy, 642 F.2d 430, 209 USPQ 48 (CCPA 1981). However, the law does not distinguish between claims drawn to a compound and claims drawn to a pharmaceutical composition comprising the compound. The only question is whether the claim recites a therapeutic use.

Applicants again direct the Examiner's attention to MPEP 2164.01(c), which recites the appropriate standard for enablement of a composition:

> If a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, 35 U.S.C. 112 is satisfied. In re Johnson, 282 F.2d 370, 373, 127 USPQ 216, 219 (CCPA 1960); In re Hitchings, 342 F.2d 80, 87, 144 USPQ 637, 643 (CCPA 1965). See also In re Brana, 51 F.2d 1560, 1566, 34 USPQ2d 1437, 1441 (Fed. Cir. 1993).

Applicants respectfully submit that the Examiner has failed to present a reasoned basis for her position that the *in vitro* experiments disclosed in the specification, combined with the knowledge available to the ordinarily skilled artisan, do not provide adequate expectation of success in achieving a beneficial result in administering a pharmaceutical composition comprising HVEM protein, for example to a herpesvirus-infected individual.

This is particularly true when the appropriate standard for enablement of a composition claim is taken into consideration. Accordingly, Applicants submit that the Examiner has not met her burden of establishing a *prima facie* case of lack of enablement.

Even If the Examiner Did Established A *Prima Facie* Case of Non-Enablement, the Examiner Has Not Provided a Basis for Rejecting Applicants' Rebuttal

Assuming, *arguendo*, that the Examiner did establish a *prima facie* case of lack of enablement, Applicants submit that the Declaration of Dr. Abbie Celniker under 37 C.F.R. § 1.132, which discusses how the skilled artisan at the time of the effective filing date of the present application would expect that a pharmaceutical composition comprising HVEM protein would be suitable for treating or preventing herpes virus infection by sequestering the virus's gD protein, is sufficient to rebut any such *prima facie* case.

The Examiner has deemed the Celniker Declaration to be unpersuasive. In particular, the Examiner concludes that "[w]hile it may be so that recombinant HVEM would bind to and sequester HSV1 particles and prevent their binding to cellular HVEM and other cellular receptor, and that herpesvirus gD protein binds HVEM and other cellular receptors through the same gD region, these results were obtained *in vitro* and no bases has been established for extrapolating results obtained in this particular system to a reasonable expectation for success in achieving a beneficial result in treating human viral infections."

The Examiner's skepticism is unfounded. In particular, the Examiner has not cited to any support for this position, merely an opinion that contradicts the reasoned conclusion of Applicants' expert. The rejection of the claims based on the Examiner's opinion, without additional evidence, is impermissible. *See, e.g.*, In re Zeidler, 682 F.2d 961, 967 (CCPA 1982).

Additional Basis of Enablement of the Claimed Invention

When a claim is drawn to a composition but does not recite a specific use of the composition, any objective disclosed in the specification and enabled is sufficient to meet the requirement of the "how-to-use" prong of 35 U.S.C. § 112, first paragraph. Raytheon Company vs. Roper Corporation, 724 F.2d 951, 958 (Fed. Cir. 1983). *See also* MPEP 2164.01(c):

> [W]hen a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on how to use. If multiple

> uses for claimed compounds or compositions are disclosed in the application, then an enablement rejection must include an explanation, sufficiently supported by the evidence, why the specification fails to enable each disclosed use. In other words, if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention.

Claims 1-5 are not limited by any specific use. Thus, any enabled use would be sufficient to support the claims.

In addition to the contemplated therapeutic use of a pharmaceutical composition comprising an HVEM polypeptide, the specification clearly teaches the use of such pharmaceutical compositions for immunizing animals to produce anti-HVEM antibodies. For example, the specification on page 24, last paragraph and page 25, fourth paragraph teaches pharmaceutical compositions, including pharmaceutical compositions comprising HVEM polypeptides and adjuvants. The specification further teaches on page 22, first full paragraph, the use of compositions comprising HVEM polypeptides and adjuvants, *i.e.*, pharmaceutical compositions comprising HVEM, to immunize animals for the production of anti-HVEM antibodies.

Accordingly, the specification teaches the use of pharmaceutical compositions for the production of HVEM antibodies. This is a sufficient utility to satisfy the how-to-use requirement of 35 U.S.C. § 112, first paragraph. Ex Parte Barnett, 2000 WL 33723405, at *3 (BPAI 2000).

Conclusion

In view of the remarks above, Applicants submit that the specification as filed provides sufficient teaching to meet the how-to-use requirement of Section112 for the claimed pharmaceutical compositions. Applicants respectfully assert that the rejection is improper and, as such, Applicants request that the rejection of claims 1-5 under 35 U.S.C. §112, first paragraph, be withdrawn.

DOUBLE PATENTING REJECTION

Claims 1-5 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-4 of U.S. Patent No. 6,303,336.

As discussed in the Response to Office Action submitted on August 5, 2002, and while not admitting that the claims of the above-identified patent application are not

patentably distinct from the claims of U.S. Patent No. 6,303,336, Attorneys for Applicants hereby state that a Terminal Disclaimer under 37 C.F.R. § 1.321(b) will be supplied to the Patent and Trademark Office when the application is indicated to be in form for grant but for a Terminal Disclaimer. Applicants request that this rejection be held in abeyance until allowable subject matter is indicated.

CONCLUSION

Applicants respectfully request consideration of the foregoing remarks. Applicants believe the claims to be in condition for allowance.

Respectfully submitted,

PENNIE & EDMONDS LLP

Date: April 18, 2003

By: Laura A. Coruzzi
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Limited Recognition Under
37 CFR § 10.9(b)
Copy of Certificate Enclosed

BEFORE THE OFFICE OF ENROLLMENT AND DISCIPLINE
UNITED STATE PATENT AND TRADEMARK OFFICE

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Expires: June 19, 2003

Harry I. Moatz
Director of Enrollment and Discipline